510(k) Summary of Safety and Effectiveness for the Hoffmann® 30 Degree Pelvic Double Ball Joint

Proprietary Name:	Hoffmann® 30 Degree Pelvic Double Ball Joint
Common Name:	External Fixation Frame Component
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Regulatory Class:	Class II
Device Product Code:	87 LXT
For Information contact:	Karen Ariemma, Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 831-5718 Fax: (201) 831-6038
Date Summary Prepared:	August 8, 2002

Intended Use:
This submission describes an external fixation frame component when used together with the components of the Hoffmann® External Fixation System, Hoffmann® II External Fixation System and Monotube Triax™ External Fixation System and in conjunction with Apex® Pins, creates an external fixation construct. External fixation frames provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

Description:
The subject Hoffmann® 30 Degree Pelvic Double Ball Joint is a modification of the Hoffmann® 5 Hole Ball Joint. The modification involves lengthening the clamp, adding an additional ball joint, modifying the pin interface and tilting the pin holding portion of the clamp by 30 degrees.

Substantial Equivalence:
Equivalency of this device is based on similarities in intended use, materials and design to the Hoffmann® 5 Hole Ball Joint. Testing has been conducted on the Hoffmann® 30 Degree Pelvic Double Ball Joint demonstrating substantial equivalence to the predicate Hoffmann® 5 Hole Ball Joint.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K022651

Trade Name:	Hoffmann® 30 Degree Pelvic Double Ball Joint
Regulation Number:	21 CFR 888.3030
Regulation Name:	Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class:	Class II
Product Code:	LXT
Dated:	August 8, 2002
Received:	August 9, 2002

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022651

Device Name: Hoffmann® 30 Degree Pelvic Double Ball Joint

Indications For Use:

The Hoffmann® 30 Degree Pelvic Double Ball Joint is intended to be used with the components of the Hoffmann® External Fixation System, Hoffmann® II External Fixation System, Monotube® TRIAX™ External Fixation System and in conjunction with Apex® Pins. This device is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts, or other means of internal fixation. The indications for use of external fixation devices include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022651